Health Committee 1

Amendment No. 1 to HB0137

Sexton C
Signature of Sponsor

AMEND Senate Bill No. 429 House Bill No. 137*

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, is amended by deleting part 5 and substituting the following:

63-10-501.

As used in this part:

(1) "Anti-rejection drug" means a prescription drug that suppresses the immune system to prevent or reverse rejection of a transplanted organ;

(2) "Board" means the board of pharmacy;

(3) "Cancer drug" means a prescription drug that is used to treat any of the following:

(A) Cancer or the side effects of cancer; or

(B) The side effects of any prescription drug that is used to treat cancer or the side effects of cancer;

(4) "Controlled substance" means the same as defined in § 39-17-402;

(5) "Department" means the department of health;

(6) "Donor" means a person, a pharmacy, or medical facility as well as any drug manufacturer or wholesaler licensed by the board of pharmacy, who donates prescription drugs to a repository program approved pursuant to this part;

(7) "Eligible Individual" means an indigent person or an uninsured person who meets all other criteria established by board rule;

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(8) "Indigent" means a person with an income that is below two hundred percent (200%) of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States department of health and human services;

(9) "Medical facility" means any of the following:

(A) A physician's office;

(B) A hospital;

(C) A health clinic;

(D) A nonprofit health clinic, which includes a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic, as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;

(E) A free clinic as defined in § 63-6-703;

(F) A charitable organization as defined in § 48-101-501; or

(G) A nursing home as defined in § 68-11-201;

(10) "Pharmacy" means a pharmacy as defined in § 63-10-204;

(11) "Prescription drug" means the same as defined in § 63-10-204, except the drug is only tablet or capsule form, and includes cancer drugs and anti-rejection drugs, but does not include controlled substances and drugs covered by the risk evaluation and mitigation strategy program of the federal food and drug administration; and

(12) "Supplies" means the supplies necessary to administer the prescription drugs donated.

63-10-502.

(a)

(1) The department of health, in cooperation with the board of pharmacy, may promulgate rules to establish and enforce a prescription drug donation repository program under which a person or organization may donate prescription drugs and supplies for use by an organization that has received a determination of exemption from the United States internal revenue service pursuant to 26 U.S.C. § 501(c)(3), and that meets eligibility criteria specified by rule for administering the program.

(2) Enforcement authority for rules promulgated pursuant to this part shall vest in the board of pharmacy.

(3) Organizations who administer a drug donation repository program shall report the following data to the department every year:

(A) Number of donors during the reporting year;

(B) Number of donations during the reporting year;

(C) List of prescription drugs and supplies donated during the reporting year;

(D) Number of people who received donations of prescription drugs or supplies during the reporting year;

(E) Total number of prescription drugs and supplies dispensed during the reporting year; and

(F) Total cost to eligible individuals who received donations during the reporting year.

(4) Rules promulgated pursuant to this part shall specify the format and method of transmission for data reported pursuant to subdivision (a)(3).

(b) Donations of prescription drugs and supplies under the program may be made directly to the repository program as required by the department or on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements established by the department. Donations of prescription drugs and supplies may be made by mail.

(c) A medical facility or pharmacy may charge an individual who receives a prescription drug or supplies a handling fee that does not exceed an amount established by rule.

(d) A medical facility or pharmacy that receives prescription drugs or supplies may distribute the prescription drugs or supplies to another eligible medical facility or pharmacy for use pursuant to the program.

(e) Participation in the program is voluntary.

63-10-503.

(a) A prescription drug or supplies may be accepted and dispensed under the prescription drug donation repository program if all of the following conditions are met:

(1) The prescription drug is in its original sealed and tamper-evident packaging. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit dose packaging remains intact;

(2) The prescription drug or supplies are inspected before the prescription drug or supplies are dispensed by a licensed pharmacist employed by or under contract with the medical facility or pharmacy, and the licensed pharmacist determines that the prescription drug or supplies are not adulterated or misbranded; and

(3) The prescription drug or supplies are prescribed by a healthcare practitioner for use by an eligible individual and are dispensed by a pharmacist.

(b) A prescription drug or supplies donated under this part shall not be resold.

(c)

(1) If a donor receives official notice of a recall of a prescription drug donated pursuant to this part, the donor shall make every effort, as required by rule, to notify the repository program to whom the drugs were donated of the recall.

(2) If an organization who is administering a drug repository program receives official notice of a recall of a prescription drug donated pursuant to this party, the organization shall make every effort as required by rule, to notify the pharmacy, medical facility, or patient, if known, to whom such donated drugs were dispensed, of the recall.

(3) Any donor or drug repository program who receives notice of a recall shall dispose of all recalled prescription drugs pursuant to board of pharmacy rules.

(d) A prescription drug dispensed through the prescription drug donation repository program is not eligible for reimbursement under the medical assistance program.

(e) The department shall adopt rules establishing all of the following:

(1) Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, including all of the following:

(A) Eligibility criteria for participation by medical facilities and pharmacies;

(B) Standards and procedures for accepting, safely storing, and dispensing donated prescription drugs and supplies;

(C) Standards and procedures for inspecting donated prescription drugs to determine if the prescription drugs are in their original sealed and tamper-evident packaging, or if the prescription drugs

are in single-unit doses or blister packs and the outside packaging is opened, if the single-unit dose packaging remains intact; and

(D) Standards and procedures for inspecting donated prescription drugs and supplies to determine that the prescription drugs and supplies are not adulterated or misbranded;

(2) Additional eligibility criteria for indigent or uninsured persons;

(3) Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program;

(4) A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate eligibility;

(5) The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program; and

(6) A list of prescription drugs that the prescription drug donation repository program will accept.

63-10-504.

(a) Except for gross negligence, willful misconduct, or bad faith, a drug manufacturer is not civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(b) Except as provided in subsection (d), a medical facility or another person who is not a drug manufacturer subject to subsection (a) is not civilly liable or subject to criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part except due to its own gross negligence,

willful misconduct, or bad faith. The medical facility or other person who is not a drug manufacturer subject to subsection (a) is also exempt from disciplinary action related to the facility's or person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this part.

(c) Except for gross negligence, willful misconduct, or bad faith, the department of health or the board of pharmacy shall not be civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property resulting from matters related to the donation, acceptance, distribution, or dispensing of a prescription drug donated pursuant to this part.

(d) The immunity and exemption provided in subsections (b) and (c) do not extend to the following:

(1) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(2) Acts or omissions outside the scope of the program.

63-10-505.

This part shall not restrict the use of samples by a physician or other person legally authorized to prescribe drugs pursuant to this title during the course of the physician's or other person's duties at a medical facility or pharmacy.

63-10-506.

This part does not authorize the resale of prescription drugs by any person.

63-10-507.

A medical facility or pharmacy may not dispense a prescription drug after the expiration date of the drug.

63-10-508.

Notwithstanding this title or title 68, or any rule, a long-term care facility licensed under title 68 may donate prescription drugs to the repository program established by this part.

63-10-509.

The department of health, in consultation with the board, is authorized to promulgate rules to effectuate the purposes of this part. The rules shall be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

63-10-510.

Notwithstanding this part or the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, any rule promulgated to implement the provisions of this part shall be provided to the chairs of the health committee of the house of representatives and the health and welfare committee of the senate by the secretary of state, after approval by the attorney general and reporter, at the same time the text of the rule is made available to the government operations committees of the senate and the house of representatives for purposes of conducting the review required by § 4-5-226 in order for the health committee of the house of representatives and the health and welfare committee of the senate to be afforded the opportunity to comment on the rule.

SECTION 2. If any provision of this act or its application to any person or circumstance is held invalid, then the invalidity shall not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end the provisions of this act shall be severable.

SECTION 3. For purposes of promulgating rules, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect on January 1, 2018, the public welfare requiring it.